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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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YOUNG & THOMPSON
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EXAMINER	
ML, QIUWEN	
ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
05/13/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/580,190	BOMBARDELLI, EZIO	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-15 and 17-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6-15, and 17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

In view of the Appeal Brief filed on 3/24/2010, PROSECUTION IS HEREBY REOPENED. The new 112, 1st rejection, 112, 2nd rejection, and 103 rejections under Giampapa, Tagashira et al, Mimica-Dukic et al, Rosa et al, or Tripathi et al are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Terry A. McKelvey/
Supervisory Patent Examiner, Art Unit 1655

Claims 1, 6-15, and 17-25 are pending. **Claims 1, 6-15, and 17-25 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 112, 1st New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-15, and 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 1, 15, and 24 recite "100 mg anthocyanodises, 100 mg procyanidins, or 100 mg of the phloroglucinols" in the claims. However, the specification fails to provide any support regarding the description of "100 mg" (last three lines of the claims). Therefore, it is not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, Applicant had possession of the "100 mg anthocyanodises, 100 mg procyanidins, or 100 mg of the phloroglucinols" in the composition of the invention. Thus, the subject matter of "100 mg" is a new matter that needs to be cancelled.

Claim 1 recites "Compositions comprising: a) anthocyanosides, procyanidins and phloroglucinols; b) anthocyanosides and phloroglucinols; and c) procyanidins and phloroglucinols, for the treatment of the affections of the oral cavity and upper respiratory tract…". However, the specification only supports the possession of a composition comprising a), b), **or** c); but failed to provide any support for the a composition comprising a), b), **and** c) (or b) **and** c) as recited in claim 24). Claims 15, 24, and 25 are rejected for the same reason.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, first paragraph for the reasons set forth above.

Applicant argues that "However, page 1, lines 20-22 of the specification teaches 1 to 200 mg of the anthocyanosides, 1 to 200 mg of the procyanidins, and 1 to 200 of the phloroglucinols. The 100 mg limitation (although not explicitly stated) is clearly within the 1 to 200 mg range. The propriety of the "100 mg" limitations is clearly supported by case law. For example, in *In re Wertheim,* 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25% - 60%" and specific examples of "36%" and "50%." A corresponding new claim limitation to 'at least 35%" did not meet the description requirement because the phrase "at least" had no upper limit and caused the claim to read literally on embodiments outside "25% to 60%" range, however a limitation to "between 35% and 60%" did meet the description requirement" (page 11, paragraphs 3-5 bridging page 12).

This is not found persuasive. The specification teaches the broad range of 1 to 200 mg of anthocyanosides, procyanidins, phloroglucinols. However, amending claims from "1 to 200 mg" to "100 mg" changes the scope of the invention, and either broadening the scope or narrowing the scope of the invention without support in the application as filed is considered as new matter, especially when the specification does not teach "100 mg" anywhere in the specification, or in any of the examples.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-15, and 17-25 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "Compositions comprising: a) anthocyanosides, procyanidins and phloroglucinols; b) anthocyanosides and phloroglucinols; and c) procyanidins and phloroglucinols, for the treatment of the affections of the oral cavity and upper respiratory tract…". The recitation is very confusing. First of all, Applicant is only entitled to claim one invention in a claim, not three different ones as a combined group of compositions that is not in an alternative form, and Applicant does not have the support to have a kit comprising three compositions. Secondly, if they were intended as a combined composition the components anthocyanosides, procyanidins and phloroglucinols as recited in composition a) encompass the components in composition b) and the components in composition c), thus it is redundant to recite the components in compositions b) and c). Claims 15, 24, and 25 are rejected for the same reason.

Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6-8, 15, 17-19, 24, and 25 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa (US 5,895,652), in view of Tagashira et al (Tagashira et al, Antioxidative activity of hop bitter acids and their analogues, Bioscience, biotechnology, and biochemistry, (1995 Apr) Vol. 59, No. 4, pp. 740-2).

Giampapa teaches a method of providing nutritional supplements to a human subject in the form of morning, mid-day, and evening comestible having a suitable geometry in which: (i) A morning comestible comprising: A. an anti-oxidant mix comprising: (a) vegetable complex, including: beta-carotene, 25,000 IU, lycopene extract, 300 mg., lutein, 700 mg., broccoli (preferably 22:1 concentrate), 200 mg., cabbage (preferably freeze dried), 500 mg., carrot powder, 200 mg., and tomato powder, 200 mg. (b) an ascorbate-citrus antioxidant complex, including: Vitamin C (from calcium, magnesium and niacinamide ascorbate), 1250 mg., Vitamin C (ascorbic acid), 1250 mg., ascorbyl palmitate (preferably fat soluble), 250 mg., acerola juice powder (a natural form of Vitamin C), 300 mg., citrus bioflavinoids, 250 mg., hesperidin complex, 250 mg., and bromelanin, 15 mg.; (c) a herbal anti-oxidant complex, including: **grape seed extract (thus the same as the claimed *Vitis vinifera*), 95% proanthcyanidin, 20**

mg., bilberry extract (thus the same as the claimed *Vaccinum myrtillus*), 25% anthocyanin, 10 mg., and milk thistle extract, 20 mg.; 500 IU vitamin E, etc (col 10, Claim 1).

Giampapa does not teach the incorporation of phloroglucinols derived from Hypericum spp., Myrtus spp. or Humulus lupulus extracts; neither does Giampapa teach the composition contain at least one of 100 mg anthocyanosides, 100 mg of the procyanidins, or 100 mg of the phloroglucinols; or the claimed amount of humulones and lupulones in alpha acid or beta-acids.

Tagashira et al teach hop bitter acids, humulones (1) (thus alpha-acids, thus phloroglucinols) and lupulones (2) (the R group including colupulone, thus beta-acids, thus phloroglucinols), were shown to have potent DPPH radical scavenging activity (RSA) and lipid peroxidation inhibitory activity (LIA) (see Abstract). Tagashira et al also teach the radical scavenging activity of humulone and lupulone are nearly equivalent to those of two natural antioxidant, alpha-tocopherol and ascorbic acid. As for lipid peroxidation, humulone and lupulone are superior to natural antioxidants by about 10-100 times (page 740, 2nd paragraph, 3rd paragraph).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate the alpha-acids and beta-acids humulones (1) and lupulones (2) from Tagashira et al into the anti-oxidant composition of Giampapa since Tagashira et al teach of humulone and lupulone are superior to natural antioxidants by about 10-100 times alpha-tocopherol and ascorbic acid. Therefore, one of the ordinary skills in the art would have been motivated to incorporate humulone and lupulone from Tagashira et al to enhance the antioxidant activity of Giampapa. Since both of the references yielded beneficial results in

antioxidant activity, one of ordinary skill in the art would have been motivated to combine the teachings of the references together.

Regarding to the claimed amount of at least one of 100 mg anthocyanosides, 100 mg of the procyanidins, or 100 mg of the phloroglucinols, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisans. Since Giampapa teaches varieties of antioxidants in the composition, it would have been obvious for one of the ordinary skills in the art to vary the amount of antioxidants in the composition according to the aging condition of the subject.

Regarding to the claimed amount of humulones and lupulones in alpha acid or beta-acids, it would have been obvious for one of the ordinary skills in the art to use either pure humulones and lupulones compounds or the alpha-acids or beta-acids enriched fractions that contain humulones and lupulones for its antioxidant activity, the percentage of humulones and lupulones in the alpha acids or beta acids would be varied according to the species of hops, the harvest season of the hops, or the isolation methods of the fractions.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1, 6-8, 13-15, 17-19, 24, and 25 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa and Tagashira et al as applied to claims 1, 6-8, 15, 17-19, 24,

and 25 above, and further in view of Mimica-Dukic et al (Mimica-Dukic et al, Antimicrobial and antioxidant activities of three Mentha species essential Oils, Planta medica, (2003 May) Vol. 69, No. 5, pp. 413-9).

The teachings of Giampapa and Tagashira et al are set forth above and applied as before.

The combination of Giampapa and Tagashira et al do not specifically teach the incorporation of essential oil mint oil into the composition.

Mimica-Dukic et al teach the present study describes the antimicrobial activity and free radical scavenging capacity (RSC) of essential oils from Mentha aquatica L., Mentha longifolia L., and Mentha piperita L (thus mint oil). The chemical profile of each essential oil was determined by GC-MS and TLC. The free radical scavenging capacity (RSC) was evaluated by measuring the scavenging activity of the essential oils on the 2,2-diphenyl-1-picrylhydrazyl (DPPH) and OH radicals. All examined essential oils were able to reduce DPPH radicals into the neutral DPPH-H form, and this activity was dose-dependent. However, only the M. piperita oil reduced DPPH to 50 % (IC50 = 2.53 microg/mL). The M. piperita essential oil also exhibited the highest OH radical scavenging activity, reducing OH radical generation in the Fenton reaction by 24 % (pure oil) (see Abstract).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate the essential oils from Mentha aquatica L., Mentha longifolia L., and Mentha piperita (mint oil) from Mimica-Dukic et al into the anti-oxidant composition of Giampapa since Mimica-Dukic et al teach the essential oils from Mentha aquatica L., Mentha longifolia L., and Mentha piperita (mint oil) have antioxidant activity. Therefore, one of the ordinary skills in the art would have been motivated to incorporate the essential oils from

Mentha aquatica L., Mentha longifolia L., and Mentha piperita from Mimica-Dukic et al to enhance the antioxidant activity of Giampapa. Since all of the references yielded beneficial results in antioxidant activity, one of ordinary skill in the art would have been motivated to combine the teachings of the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1, 11, 12, 15, 17, and 22-25 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa (US 5,895,652), in view of Rosa et al (Rosa et al, Antioxidant activity of oligomeric acylphloroglucinols from Myrtus communis L., Free radical research, (2003 Sep) Vol. 37, No. 9, pp. 1013-9).

Giampapa teaches a method of providing nutritional supplements to a human subject in the form of morning, mid-day, and evening comestible having a suitable geometry in which: (i) A morning comestible comprising: A. an anti-oxidant mix comprising: (a) vegetable complex, including: beta-carotene, 25,000 IU, lycopene extract, 300 mg., lutein, 700 mg., broccoli (preferably 22:1 concentrate), 200 mg., cabbage (preferably freeze dried), 500 mg., carrot powder, 200 mg., and tomato powder, 200 mg. (b) an ascorbate-citrus antioxidant complex, including: Vitamin C (from calcium, magnesium and niacinamide ascorbate), 1250 mg., Vitamin C (ascorbic acid), 1250 mg., ascorbyl palmitate (preferably fat soluble), 250 mg., acerola juice powder (a natural form of Vitamin C), 300 mg., citrus bioflavinoids, 250 mg., hesperidin

complex, 250 mg., and bromelanin, 15 mg.; (c) a herbal anti-oxidant complex, including: **grape seed extract (thus the same as the claimed *Vitis vinifera*), 95% proanthcyanidin, 20 mg., bilberry extract (thus the same as the claimed *Vaccinum myrtillus*), 25% anthocyanin, 10 mg**., and milk thistle extract, 20 mg.; 500 IU vitamin E, etc (col 10, Claim 1).

Giampapa does not teach the incorporation of phloroglucinols derived from Hypericum spp., Myrtus spp. or Humulus lupulus extracts; neither does Giampapa teach the composition contain at least one of 100 mg anthocyanosides, 100 mg of the procyanidins, or 100 mg of the phloroglucinols; incorporation of phloroglucinols from Myrtus communis, or the claimed amount of myrtucommulone or the extraction condition of Myrtus communis in claims 11 and 22.

Rosa et al teach the use of myrtle (Myrtus communis L.) as a culinary spice and as a flavoring agent for alcoholic beverages is widespread in the Mediterranean area, and especially in Sardinia. Myrtle contains unique oligomeric non-prenylated acylphloroglucinols, whose antioxidant activity was investigated in various systems. Both semimyrtucommulone (1) and myrtucommulone A (2) showed powerful antioxidant properties, protecting linoleic acid against free radical attack in simple in vitro systems, inhibiting its autoxidation and its $FeCl_3$- and EDTA-mediated oxidation. While both compounds lacked pro-oxidant activity, semimyrtucommulone was more powerful than myrtucommulone A, and was further evaluated in rat liver homogenates for activity against lipid peroxidation induced by ferric-nitrilotriacetate, and in cell cultures for cytotoxicity and the inhibition of TBH- or FeCl3-induced oxidation. The results of these studies established semimyrtucommulone as a novel dietary antioxidant lead (see Abstract).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate the myrtucommulone from Rosa et al into the anti-oxidant composition of Giampapa since Rosa et al teach acylphloroglucinols showed powerful antioxidant properties, protecting linoleic acid against free radical attack in simple in vitro systems, inhibiting its autoxidation and its $FeCl_3$- and EDTA-mediated oxidation. Therefore, one of the ordinary skills in the art would have been motivated to incorporate acylphloroglucinols from Rosa et al to enhance the antioxidant activity of Giampapa. Since both of the references yielded beneficial results in antioxidant activity, one of ordinary skill in the art would have been motivated to combine the teachings of the references together.

Regarding to the claimed amount of at least one of 100 mg anthocyanosides, 100 mg of the procyanidins, or 100 mg of the phloroglucinols, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisans. Since Giampapa teaches varieties of antioxidants in the composition, it would have been obvious for one of the ordinary skills in the art to vary the amount of antioxidants in the composition according to the aging condition of the subject.

Regarding to the claimed amount of myrtucommulone in Myrtus communis extract, one of the ordinary skills in the art would have been motivated to use either the pure myrtucommulone compound or the myrtucommulone containing Myrtus communis extract for its antioxidant activity, the percentage of myrtucommulone in Myrtus communis extract would be varied according to the species of Myrtus communis, the harvest season of Myrtus communis, or the isolation method of the fractions.

Regarding to the extraction condition recited in claims 11 and 22, the MPEP states the following: "[E]ven though product-by-process claims are limited by and defined by the process determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process...The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product" (see MPEP 2113 [R-1]). It is deemed that the product *Myrtus communis* extract disclosed by Rosa et al is not materially differently from the claimed *Myrtus communis* extract in claims 11 and 22, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1, 9, 10, 15, 17, 20, 21, 24, and 25 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa (US 5,895,652), in view of Tripathi et al (Tripathi et al, Antioxidant property of Hypericum perforatum (L.) of Indian origin and its comparison with established Medhya rasayanas [Bacopa monnieri and Nardostachys jatamansi] of Ayurvedic medicine, Current Science, (1999) Vol. 76, No. 1, pp. 27-29).

Giampapa teaches a method of providing nutritional supplements to a human subject in the form of morning, mid-day, and evening comestible having a suitable geometry in which: (i) A morning comestible comprising: A. an anti-oxidant mix comprising: (a) vegetable complex, including: beta-carotene, 25,000 IU, lycopene extract, 300 mg., lutein, 700 mg., broccoli (preferably 22:1 concentrate), 200 mg., cabbage (preferably freeze dried), 500 mg., carrot powder, 200 mg., and tomato powder, 200 mg. (b) an ascorbate-citrus antioxidant complex, including: Vitamin C (from calcium, magnesium and niacinamide ascorbate), 1250 mg., Vitamin C (ascorbic acid), 1250 mg., ascorbyl palmitate (preferably fat soluble), 250 mg., acerola juice powder (a natural form of Vitamin C), 300 mg., citrus bioflavinoids, 250 mg., hesperidin complex, 250 mg., and bromelanin, 15 mg.; (c) a herbal anti-oxidant complex, including: **grape seed extract (thus the same as the claimed *Vitis vinifera*), 95% proanthcyanidin, 20 mg., bilberry extract (thus the same as the claimed *Vaccinum myrtillus*), 25% anthocyanin, 10 mg.**, and milk thistle extract, 20 mg.; 500 IU vitamin E, etc (col 10, Claim 1).

Giampapa does not teach the incorporation of phloroglucinols derived from Hypericum spp., Myrtus spp. or Humulus lupulus extracts; neither does Giampapa teach the composition contain at least one of 100 mg anthocyanosides, 100 mg of the procyanidins, or 100 mg of the phloroglucinols; or the claimed amount of phloroglucinols in Hypericum perforatum extract.

Tripathi et al teach the antioxidant property of Hypericum perforatum. Tripathi et al teach in this paper, for the first time, we have investigated its potential effect on superoxide radical-scavenging, -OH radical-trapping, etc. The results have shown that this plant could be used as an antioxidant in medicine (page 27, 2nd column, 2nd paragraph). Fresh H. perforatum shoots were collected. It was powdered and extracted with ethanol for 30 h in a soxhlet

apparatus. The extract was evaporated under low pressure by using Buchitype rotary evaporator. The concentrated extract was kept in a vacuum desiccator till the constant weight of solvent-free extract was attained (page 27, 3rd column, 2nd paragraph) (thus the ethanol extract of Hypericum perforatum necessarily contains the claimed phloroglucinols).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate the Hypericum perforatum extract from Tripathi et al into the anti-oxidant composition of Giampapa since Tripathi et al teach Hypericum perforatum extract has antioxidant activity. Therefore, one of the ordinary skills in the art would have been motivated to incorporate the Hypericum perforatum extract from Tripathi et al to enhance the antioxidant activity of Giampapa. Since both of the references yielded beneficial results in antioxidant activity, one of ordinary skill in the art would have been motivated to combine the teachings of the references together.

Regarding to the claimed amount of at least one of 100 mg anthocyanosides, 100 mg of the procyanidins, or 100 mg of the phloroglucinols, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisans. Since Giampapa teaches varieties of antioxidants in the composition, it would have been obvious for one of the ordinary skills in the art to vary the amount of antioxidants in the composition according to the aging condition of the subject.

Regarding to the claimed amount of phloroglucinols in Hypericum perforatum extract, the amount of phloroglucinols would be varied according to the species of Hypericum

perforatum, the harvest season of Hypericum perforatum, or the isolation method of the Hypericum perforatum extract.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "Distinctions of the present invention over the applied art references have been made of record in the application. These distinctions pointed out the inability of the applied art to assert prima facie unpatentability of the present invention and the unexpected results rebutting any unpatentability set forth in the signed Declaration filed May 7, 2008. For brevity these distinctions are not repeated here. Further, independent claims 1 and 15 of the present invention have been instantly amended to better conform with the unexpected results set forth in the signed Declaration filed May 7, 2008. It is also believed that the newly presented claims are also covered by the unexpected results set forth in the Declaration, including combinations of A+B+C and B+C such as is set forth in Tables 1 and 2, reproduced below" (page 12, 3rd to 5th paragraph).

This is not found persuasive. The Declaration filed on 5/7/2008 is not commensurate with the scope of the current claims and thus do not overcome the rejections based upon unexpected results. First of all, according to the Declaration, it is required that components A+B+C or B+C are all present in the composition so as to accomplish unexpected result. However, current claim 1 only requires at least one of 100 mg anthocyanodises, 100 mg procyanidins, or 100 mg of the

phloroglucinols. The Declaration does not show that at least one of the A, B or C component at 100 mg has unexpected result. Secondly, the Examiner offered allowance through Examiner's amendment based on 200 mg of anthocyanodises, 200 mg procyanidins, and 200 mg of the phloroglucinols all present in the composition, Applicant declined the offer. Thirdly, the currently amended claims recite "100 mg anthocyanodises, 100 mg procyanidins, or 100 mg of the phloroglucinols" in the claims, and "100 mg" is a new matter that is not supported by the specification, thus the amended claims are not allowable.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Qiuwen Mi/

Examiner, Art Unit 1655